



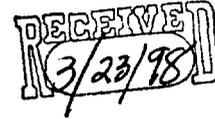
PHARMANEX

A Natural Healthcare Company

Pharmanex, Inc.
625 Cochran Street
Simi Valley, California
93065-1939
805.582.9300
Fax 805.582.9301

March 23, 1998 6 '98 MAR 31 P3:07

BY FEDERAL EXPRESS



Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C. St. S.W.
Washington, DC 20204

RE: Notification for Certain Types of Statements on Dietary Supplements.

Dear Sir or Madam:

As required by Section 403 (r)(6)(c) of the Food, Drug and Cosmetic Act, Pharmanex Inc., 625 Cochran Street, Simi Valley, California 93065-1939, intends to market a dietary supplement product with the following labeling statements of nutritional support:

Product identified as **EstroCare™**, containing standardized extracts of Black Cohosh and a proprietary strain of *Cordyceps sinensis*, with the following labeling statements:

1. Natural menopausal support.
2. Helps with menopausal discomfort.
3. Promotes healthy hormonal balance.
4. Reduces symptoms of fatigue.
5. EstroCare™ meets the demands of today's woman by providing the nutritional support for a smooth transition through menopause.
6. EstroCare™ is a gentle and beneficial way to promote hormonal balance.
7. By helping normalize hormonal functions, it provides support for handling the physical and emotional discomforts associated with menopause and the menstrual cycle.
8. EstroCare™ can also provide benefits to younger women by helping to balance menstrual cycles.
9. The Black Cohosh extract in EstroCare™ works by relaying messages to the hypothalamus in the brain to stop the pituitary from producing luteinizing hormone (LH)—often associated with menopausal conditions.

975-0162

also see docket 975-0163

LET 1426
57887



PHARMANEX

A Natural Healthcare Company

10. In Europe, Black Cohosh extract, such as that in EstroCare™, has been effectively used for the management of menopausal conditions.
11. In clinical studies, the majority of women receiving a standardized formulation of Black Cohosh, such as the one in EstroCare™, showed improvement in some of the physical and emotional signs associated with menopause after 4 to 8 weeks of use at recommended dosages.
12. With the addition of CordyMax™, EstroCare™ may help overcome recurring fatigue and the general loss of pleasure in everyday activities.

I certify that the information contained in this notice is complete and accurate and that Pharmanex, Inc. has substantiation that these statements are truthful and not misleading.

Sincerely,


Michael Chang
Sr. V.P. Research & Development